

**REMARKS**

Claims 15, 17-19, 21-22, 25-26 and 30-41 are pending in the application. Claims 15, 17-19, 21-22, 25-26 and 30-41 are rejected. No claims are allowed. Claims 15, 17-19, 25, 34-35, 38 and 39 have been amended. New claims 42-44 have been added. Upon entry of this response, claims 15, 17-19, 21-22, 25-26, and 30-44 will be presented for examination.

Applicants respectfully request entry of the above amendments to the claims. Claims 15, 17-19, 25, 34-35, 38 and 39 have been amended to recite the limitation that the composition is topically applied to aged human skin in an amount effective to provide an anti-ageing effect. Newly added claims 43 and 44 are specific to inhibiting the secretion of elastase present as a result of the process that produced the aged human skin and to stabilizing or scavenging free radicals present as a result of the process which produced the aged human skin, respectively. Support for the amendments can be found at least at page 4, paragraphs 2 and 4, at page 19, paragraph 2, and at page 24, first bullet point of the specification as originally filed. New claims 42-44 have been added, support for which can be found at least at page 4, paragraphs 2 and 4, and at the paragraph bridging pages 25-26 of the specification as originally filed.

No new matter has been added by this amendment.

Reconsideration of the rejections and allowance of claims 15, 17-19, 21-22, 25-26, and 30-44 in view of the following remarks are respectfully requested. As will be discussed below, these claims provide for a method of treatment of aged human skin comprising topically applying to the aged human skin a dermatopharmaceutical composition comprising an extract of leaves of a Castanea sativa plant, and at least one cosmetic and/or dermatopharmaceutical auxiliary, in an amount effective to provide an anti-ageing effect. The cited references do not contemplate such a method.

**Claim Rejections – 35 U.S.C. § 103**

Claims 15, 17-19, 21-22, 25-26, and 30-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the International Cosmetic Ingredient Dictionary and Handbook (9th ed., 2002) in view of the admitted state of the art, and further in view of Schneider (U.S. 6,184,247),

Chiej (MacDonald Encyclopedia of Medicinal Plants, 1984), and Brooks et al. (U.S. 6,191,083), with evidence provided by Chevallier (Encycl. of Herbal Medicine, 2000).

As a preliminary matter, it is not clear what specifically is being relied on when the Office Action states “the admitted state of the art.” Applicants respectfully note that when references are provided in an Information Disclosure Statement, no admission regarding the state of the prior art is made. According to MPEP § 2129 Admissions as Prior Art, “[m]ere listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims,” citing *Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354-55, 66 USPQ2d 1331, 1337-38 (Fed Cir. 2003).

According to the Examiner, Castanea sativa leaf extract is a well known herbal extract used in the cosmetic art as a skin-conditioning agent, and that it is well recognized in the art that essentially all cosmetics comprise auxiliaries and/or additives such as many of those Applicants claim (e.g., thickeners, surfactants, emulsifiers, fats, waxes, antimicrobial agents, preservatives, perfumes, and/or dyes, etc.). (Office Action at page 2).

Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. See *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), viz., (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, “there must be some articulated reasoning with some rational underpinning to support the legal

conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

### **Claim 15**

Claim 15, as amended, is directed toward a method for treatment of aged human skin comprising topically applying to the aged human skin a dermatopharmaceutical composition comprising an extract of *Castanea sativa* leaf and at least one auxiliary ingredient, in an amount effective to provide an anti-ageing effect. Newly added claim 42 is specific to application of the composition to skin showing signs of ageing. Newly added claims 43-44 are specific to inhibiting the secretion of elastase present as a result of the process that produced the aged human skin and to stabilizing or scavenging free radicals present as a result of the process which produced the aged human skin, respectively. According to the Examiner, the “International Cosmetic Ingredient Dictionary and Handbook beneficially teaches that *Castanea sativa* leaf extract is a well known herbal extract used in the cosmetic art as a skin-conditioning agent.” (Office Action at page 2).

Applicants’ invention, however, is not directed toward the use of *Castanea sativa* leaf extract as a skin-conditioning agent. Rather, Applicants’ invention is directed toward the use of *Castanea sativa* leaf extract for treatment of aged human skin. In particular embodiments, provided are the anti-ageing effects of inhibiting the secretion of elastase present as a result of the process that produced the aged human skin or stabilizing or scavenging free radicals present as a result of the process which produced the aged human skin. Another embodiment specifies that the dermatopharmaceutical composition is topically applied to skin showing signs of ageing. The International Cosmetic Ingredient Dictionary and Handbook makes specific reference to “Skin Conditioning Agent-Miscellaneous.” (International Cosmetic Ingredient Dictionary and Handbook, p. 279). According to CosmeticsInfo.org, “skin conditioning agent(s)-miscellaneous” are ingredients that enhance the appearance of dry or damaged skin by reducing flaking and restoring suppleness (<http://www.cosmeticsinfo.org/glossary.php?glossary=S>). Free-radical stabilizers and scavengers, like the Applicants’ claimed invention, on the other hand, protect the body’s cells from the damaging effects of oxidation and other ageing processes, and thereby, slow or reverse the ageing process (see pages 18-19 of the as-filed Specification).

The Examiner alleges that the claimed functional effects (i.e., anti-ageing) would be inherent upon topical application to the skin. (Office Action at page 5). The Examiner's allegation relies on a mere possibility that application of Castanea sativa leaf extract to the skin would produce anti-ageing effects. The cited art is devoid of any such teaching. Moreover, with respect to claims 43 and 44, the art further fails to provide any suggestion or teaching that Castanea sativa leaf extract produces inhibition of the secretion of elastase or free-radical stabilizing or scavenging effects. In addition, with respect to claim 42, the prior art is devoid of any showing that the dermatopharmaceutical composition is topically applied to skin showing signs of ageing. Therefore, the Examiner's allegation regarding the inherent properties of Castanea sativa leaf extract is misguided, and is an incorrect interpretation of the law.

The Federal Circuit held that "to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). The prior art is devoid of any teaching or suggestion that Applicants' invention would produce anti-ageing effects. Specifically, the art fails to teach or suggest inhibition of the secretion of elastase or free-radical stabilizing or scavenging effects observed by Applicants' invention. Thus, the allegation that any such anti-ageing effects would be inherent upon topical application to the skin is relying upon probabilities and possibilities and is not permitted.

In addition, the Federal Circuit also held that "new uses of old products or processes are indeed patentable subject matter." *Nicholas v. Perricone, M.D.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005). In this case, where Perricone claimed a new use of a composition disclosed by Pereira, the Court found that "the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent." *Id.* at 1379. The court went on to explain that "only by dismissing the explicit language of Dr. Perricone's claimed method: 'applying to the skin sunburn'," can one argue that Pereira discloses Perricone's invention; the Court found this reasoning to be misguided and vacated the district court's summary judgment of non-infringement. *Id.* The Court found that the treatment of skin sunburn was not analogous to

preventing sunburn, and, therefore, a topical composition for treating skin sunburn was a patentable new use of an old product. *Id.* Analogously with respect to the present claims, the Examiner's allegation regarding the inherent functional effects of Applicants' claimed invention goes astray because the Examiner is assuming what International Cosmetic Ingredient Dictionary and Handbook neither discloses nor renders inherent. International Cosmetic Ingredient Dictionary and Handbook is devoid of any language suggesting topical application to aged human skin to provide an anti-ageing effect. Therefore, to say that the anti-ageing effects, including the inhibition of the secretion of elastase and free-radical stabilizing or scavenging effects, are inherent, would be ignoring Applicant's explicit language of the claimed method (i.e., topically applying to the aged human skin); this would be counter to the Federal Circuit's holding in *Perricone*. Thus, Applicants submit that the claimed invention is not inherent, nor obvious, and is patentable over International Cosmetic Ingredient Dictionary and Handbook.

Furthermore, as noted by the Examiner, International Cosmetic Ingredient Dictionary and Handbook fails to disclose a topical composition containing auxiliaries or additives as presently claimed. (Office Action at page 2). International Cosmetic Ingredient Dictionary and Handbook does not teach or suggest a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide anti-ageing effects. The Examiner relies upon Schneider as allegedly teaching topical cosmetic compositions useful for treating skin which comprise, or may comprise, skin conditioners as well as one or more conventional cosmetic adjunct ingredients therein such as thickeners and/or plant extracts including witch hazel. (*Id.* at page 3.) The Examiner contends that it would have been obvious to use the teachings of Schneider to arrive at Applicants' claimed invention. Schneider, however, fails to make up for the deficiencies of the International Cosmetic Ingredient Dictionary and Handbook. Schneider does not teach or suggest a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect. Moreover, with respect to claims 43 and 44, it is also silent as to inhibition of the secretion of elastase and to stabilizing or scavenging free radicals present as a result of the process which produced the aged human skin. In addition, with respect to claim 42, it is silent as to application

of the dermatopharmaceutical composition to skin showing signs of ageing. Schneider's composition comprises from about 0.01% to 99% of an ascorbic acid derivative (Schneider at column 2, line 49-50). That Schneider additionally uses one or more conventional cosmetic adjunct ingredients in its cosmetic formulation is not relevant because International Cosmetic Ingredient Dictionary and Handbook does not teach a composition comprising an ascorbic acid derivative. Therefore, without such an ingredient being suggested in the extract described in International Cosmetic Ingredient Dictionary and Handbook, there is no rational basis on which to rely to add the auxiliary ingredients of Schneider to the extract described in International Cosmetic Ingredient Dictionary and Handbook. Even if such a combination were to be justified, which is not conceded here, there would be no expectation of success due to the ascorbic acid ingredient of Schneider being missing from the extract described in International Cosmetic Ingredient Dictionary and Handbook.

The Examiner relies upon Chiej as allegedly teaching that Castanea sativa leaves have been used as a substitute for witch hazel and illustrating a cosmetic hair shampoo comprising an extract of Castanea sativa leaves. The Examiner states that, "witch hazel is notoriously well known in the prior art to be used cosmetically to topically treat such ailments as skin abrasion, facial veins, varicose veins, and hemorrhoids, including in the form of a lotion or ointment." (*Id.*). Applicants' invention, however, is not directed to a cosmetic agent to treat veins and hemorrhoids; rather, Applicants invention is directed toward a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect. The cited art provides no evidence that witch hazel is known to provide anti-ageing effects. Likewise, no reference is made in the cited art to witch hazel as an agent for providing inhibition of the secretion of elastase or free-radical stabilizing or scavenging. As a result, in the case of Applicants' invention, Castanea sativa leaf extract is not an obvious equivalent substitution for the witch hazel extract disclosed by Schneider. The fact that Castanea sativa leaves can sometimes be a substitute for witch hazel, therefore, is irrelevant with respect to Applicants' claimed secretion of elastase inhibiting and free-radical stabilizing and scavenging composition. Moreover, because the cited art provides no evidence regarding witch hazel as an agent for providing inhibition of the secretion of elastase or free-radical stabilizing or scavenging

properties, there is no rational basis on which to rely to substitute *Castanea sativa* leaf extract for witch hazel in the composition of Schneider. Furthermore, even if such a substitution were to be justified, which is not conceded here, there would be no expectation of success because the ascorbic acid derivative of Schneider is not described in the extract of International Cosmetic Handbook and Dictionary.

The Examiner contends that it “would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include one or more auxiliaries and/or additives from among those instantly claimed (e.g., a conventional cosmetic thickener as beneficially disclosed Schneider) including a notoriously well known natural polysaccharide thickener – such as xanthan gum or guar gum (as beneficially disclosed by Brooks) within a cosmetic composition comprising the well known cosmetic conditioning agent *Castanea sativa* leaf extract.” (*Id.* at page 4). The Examiner relies on Brooks et al. as allegedly teaching natural polysaccharides as thickening agents. (*Id.* at page 3). Brooks et al., however, fail to make up for the deficiencies of the combination of International Cosmetic Ingredient Dictionary and Handbook and Schneider. Brooks et al., however, do not teach or suggest a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of *Castanea sativa* leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect. The composition of Brooks comprises (in varying amounts by weight), a thickening system, a water-soluble surfactant, optionally a cationic polymer, and water. Without such ingredients being present in the extract described in International Cosmetic Ingredient Dictionary and Handbook, there is no rational basis on which to rely to add the thickener of Brooks to the extract described in International Cosmetic Ingredient Dictionary and Handbook.

Thus, the office action has not established *prima facie* obviousness and Applicants’ invention is patentable over International Cosmetic Ingredient Dictionary and Handbook (9th ed., 2002), in view of Schneider (US 6,184,247), Chiej (MacDonald Encyclopedia of Medicinal Plants, 1984), and Brooks et al. (US 6,191,083), with evidence provided by Chevallier (Encycl. of Herbal Medicine, 2000).

Accordingly, any suggestion that the prior art disclose, teach or suggest the claimed invention would constitute improper picking, choosing, and combining various disclosures not

directly related to each other by the teachings of the cited references. One would have to pick and choose among a number of broad variables to possibly arrive at Applicants' invention. *See In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention."). Indeed, picking and choosing would most definitely lead to combinations that would not result in the claimed invention. For example, if one were to choose witch hazel, as discussed in Chiej and Chevallier, and mix it with a cosmetic thickener, such as xanthan gum or guar gum (as stated in Schneider and Brooks et al.), the result would not be Applicants' claimed invention – a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect; instead, the result would be a composition possibly useful for treating hemorrhoids.

The Federal Circuit has explicitly cautioned against the type of reasoning undertaken by the Examiner in this case. For example, the court in *Ruiz v. A.B. Chance Co.* stated:

The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result - often the very definition of invention. Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner.

357 F.3d 1270, 1275 (Fed. Cir. 2004).

In the instant case, and as cautioned against by *Ruiz*, the Examiner has used Appellants' disclosure as a roadmap to identify unrelated elements in the cited references to arrive at the claimed invention, when none of the references even remotely suggest a method of treating aged human skin comprising topically applying to the aged human skin a composition



comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect. This is the epitome of “impermissible hindsight,” and cannot support a *prima facie* case of obviousness. See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1443 (Fed. Cir. 1983) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.”).

For at least the foregoing reasons, the combination of International Cosmetic Ingredient Dictionary and Handbook (9th ed., 2002) with Schneider, Chiej, and Brooks et al., with evidence provided by Chevallier fail to disclose Applicants’ invention as claimed in claim 15, and thus, claim 15 is patentable over the cited references. Accordingly, withdrawal of this rejection is respectfully requested.

For the same reasons that claim 15 is patentable, claims 17-19, 21-22, 25-26, 30-41 and newly added claims 42-44 are patentable. Withdrawal of the rejection of these claims is also respectfully requested.

### **Claims 34-35**

Claim 34, as amended, is directed toward a method of treating aged human skin comprising topically applying to the aged human skin a composition consisting of: an extract of Castanea sativa leaf and one or more thickeners, in an amount effective to provide an anti-ageing effect. The cited art provides such a wide range of ingredients, that there is no teaching or suggestion that a composition should consist of only an extract of Castanea sativa leaf and one or more thickeners. Moreover, Schneider contains additional “active” ingredients (e.g., ascorbic acid) in conjunction with a plant extract in its compositions, which means that any combination of Schneider with the International Cosmetic Ingredient Dictionary and Handbook falls outside the scope of claims 34-35. For these additional reasons, Applicants respectfully request withdrawal of this basis for rejection.

For the same reasons that claim 34 is patentable, claim 35 is also patentable. Withdrawal of the rejection of this claim is also respectfully requested.

**Claim 38**

Claim 38, as amended, is directed toward a method of treating aged human skin comprising topically applying to the aged human skin a composition consisting of: an extract of Castanea sativa leaf, one or more thickeners, and water, in an amount effective to inhibit the secretion of elastase present or to stabilize or scavenge free radicals present as a result of the process which produced the aged human skin. As discussed above with respect to claim 15, none of the cited references disclose a method of treating aged human skin comprising topically applying to the aged human skin a composition comprising an extract of Castanea sativa leaf and at least one auxiliary ingredient in an amount effective to provide an anti-ageing effect, wherein the anti-ageing effect is inhibiting secretion of elastase or stabilizing or scavenging free radicals present as a result of the process which produced the aged human skin. Furthermore, as discussed above with respect to claims 34-35, the cited art provides such a wide range of ingredients, that there is no teaching or suggestion that a composition should consist of only an extract of Castanea sativa leaf, one or more thickeners, and water. In addition, the cited art contains additional “active” ingredients (e.g., ascorbic acid) in their compositions, which means that any combination of the cited art with International Cosmetic Ingredient Dictionary and Handbook falls outside the scope of claim 38. As a result, Applicants submit that claim 38 is not obvious over the combination of International Cosmetic Ingredient Dictionary and Handbook (9th ed., 2002) with Schneider, Chiej, and Brooks et al., with evidence provided by Chevallier, and, thus, is patentable over the cited references. Applicants respectfully request withdrawal of this rejection.

### **CONCLUSION**

It is believed that claims 15, 17-19, 21-22, 25-26, and 30-44 are now in condition for allowance, early notice of which would be appreciated. The fee for the Petition of Extension of Time for one month is included. In addition, submitted herewith is a Request for Continued Examination, together with the appropriate fee. It is believed that no other fees are due at this time. If any additional fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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